REMARKS

I. Introduction

This application is a continuation of parent application No. 10/090,121, filed February 28, 2002. Claims 1-23 are in this application. Claims 1-7 had been pending in commonly-assigned application No. 09/798,367, filed March 2, 2001 (as, consecutively, claims 1-5, 7, and 8). Claims 8-23 had been pending in common-assigned application No. 09/798,514, filed March 2, 2001 (as, consecutively, claims 1-4 and 6-17).

Claim 8 has been amended to more particularly define the invention.

The specification has been amended to add a cross reference to the parent application.

II. History of Claims 1-7 in Application No. 09/798,367

Claims 1-7, as originally filed, were variously rejected in a June 5, 2003 Final Office action issued in application No. 09/798,367. More specifically, the Examiner rejected claims 1-7 under 35 U.S.C. § 102(b) as being anticipated by Goldsteen et al. U.S. patent 5,976,178 (hereinafter "Goldsteen"). Claims 1 and 5-7 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kaster et al. U.S. patent 5,366,462 (hereinafter "Kaster").

The Examiner's rejections of claims 1-7 in the June 5, 2003 Final Office action of application No. 09/798,367 are addressed below.

III. Remarks on the Rejections of Claims 1-7 in the June 5, 2003 Final Office Action of Application No. 09/798,367

Applicants' claim 1 is directed toward a connector for use in connecting an end portion of a graft to an artificially formed aperture in the side wall of a patient's tubular body conduit so that the lumen of the graft communicates with the lumen of the conduit via a fluid-tight connection. The connector comprises an annularly continuous structure that is configured for disposition substantially concentric with the graft conduit and is annularly enlargeable. The continuous structure includes an annular array of tissue-piercing members, each having a cantilevered length great enough to pass, in use, all the way through the side wall of the graft conduit. The structure also includes a plurality of retention fingers configured to be extendable radially outwardly to engage the inside of the side wall of the patient's body conduit at locations annularly surrounding the aperture.

A. The Rejection of Claims 1-7 under 35 U.S.C. § 102(e) over Goldsteen

The Examiner rejected claims 1-7 under 35 U.S.C. § 102(e) as being anticipated by Goldsteen. This rejection has been rendered moot by the transfer of claims 1-7 into the current continuation application, which claims priority to Goldsteen. Applicants would like to point out that the inventors for application No. 09/798,367 and the current application are the same. Accordingly, applicants respectfully submit that this rejection over Goldsteen should not be issued in the current application.

B. The Rejection of Claims 1 and 5-7 under 35 U.S.C. § 102(b) over Kaster

The Examiner rejected 1 and 5-7 under 35 U.S.C. § 102(b) as being anticipated by Kaster. This rejection is respectfully traversed.

Kaster refers to a surgical staple for stapling two vessels together. The staple includes interior and exterior wall engaging members. The interior wall engaging members are pierced through an everted end portion of the graft vessel and inserted into a pre-formed hole in the patient's vessel. Both the interior and exterior wall engaging members are then deflectively bent so that sharp ends of the wall engaging members respectively pierce the inner and outer walls of the patient's vessel to staple the graft vessel and the patient's vessel together.

The Examiner contends that Kaster shows all the features of applicants' claim 1. In particular, the Examiner contends that "the ring of connecting unit (46)(see Figure 10) is piecewise continuous along the ring" and that "[t]he ring of Kaster is expandable as the gap [in connecting unit 46] is enlarged" (page 3, lines 5-7 of June 5, 2003 Final Office action). Contrary to the Examiner's contention, applicants submit that applicants' claim 1 is patentable over Kaster because Kaster fails to show a connector structure "that is annularly continuous but annularly enlargeable" as set forth by claim 1 (lines 11-12 of applicants' claim 1).

Applicants submit that Kaster fails to show or suggest either one of applicants' claimed features for a connector structure that is annularly continuous and annularly enlargeable. In stark contrast to applicants' claimed invention, Kaster's connecting unit 46 is clearly discontinuous (see FIG. 10 of Kaster) by the very nature of its formation from a linear band of material that is "curved about a mandrel or other appropriate object to cause the connecting unit (46) to assume an annular shape" (column 6, lines 5-8 of Kaster). Further, applicants submit that there is not a single showing or suggestion in Kaster of annularly enlarging connecting unit 46. And, even if such an enlargement were to be accomplished, *arguendo*, it would necessarily (as noted by the Examiner) cause an even greater discontinuity in connecting unit 46. Therefore, applicants submit that Kaster fails to show a connector structure that is both annularly continuous and annularly enlargeable.

Accordingly, for at least the foregoing reasons, applicants submit that claims 1 and 5-7 are allowable over Kaster.

IV. History of Claims 8-23 in Application No. 09/798,514

Claims 8-23, as originally filed, were variously rejected in a June 9, 2003 Final Office action issued in application No. 09/798,514. More specifically, the Examiner provisionally rejected claims 8-23 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of copending application No. 10/188,699. Claims 8, 9, 11, 12-16, 21, and 23 were rejected under 35 U.S.C. § 102(b) as being anticipated by Marin et al. U.S. patent 5,397,355 (hereinafter "Marin"), or alternatively, under 35 U.S.C. § 103(a) as being unpatentable over Marin in view of Kaster et al. U.S. patent 5,234,447 (identical parent to previously cited Kaster et al. U.S. patent 5,366,462, and therefore also referred to hereinafter as "Kaster"). Claims 8-16, 20, 21, and 23 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kaster. Claims 17-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kaster in view of Dwyer et al. European publication No. EP 0701800 (hereinafter "Dwyer"). Claim 22 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Marin in view of Kaster and Kim U.S. patent 5,676,670 (hereinafter "Kim").

Applicants acknowledge the Examiner's provisional obviousness-type double patenting rejection of claims 8-23 over claims 1 and 7 of application No. 10/188,699.

Applicants have amended claim 8 in order to more particularly define the invention.

The Examiner's rejections of claims 8-23 in the June 9, 2003 Final Office action of application No. 09/798,514 will be addressed below.

V. Remarks on the Rejections of Claims 8-23 in the June 9, 2003 Final Office Action of Application No. 09/798,514

Applicants' invention, as defined by currently amended claim 8, is directed toward a connector for use in connecting a body tissue graft to the side wall of a patient's body tissue conduit so that the lumen of the graft communicates with the lumen of the conduit through an aperture in the side wall of the conduit. The connector comprises an annular structure that is annularly continuous and has first and second axially adjacent substructures. The first substructure is configured to be disposed inside the patient's body tissue conduit and includes a plurality of annularly spaced struts. The annularly spaced struts are configured to extend from a first position in which the struts are substantially parallel to an axis with which the annular structure is substantially coaxial to a second position in which the struts are radially outward.

Applicants have amended claim 8 to specify the annularly continuous nature of the connector structure and to more particularly define the second position of the struts. As amended, claim 8 sets forth the second position of the struts as a position in which the struts are radially outward and substantially perpendicular to said axis to engage the inside of the side wall of the body tissue conduit at locations that are disposed annularly around the aperture in the conduit. Support for this amendment to claim 8 can be found, for example, in applicants' FIGS. 34 and 35, and in the written description at column 16, line 60 to column 18, line 27, and at column 17, lines 49-58. Accordingly, no new matter has been added.

A. The Rejection of Claims 8, 9, 11, 12-16, 21, and 23 under 35 U.S.C. § 102(b)/103(a) over Marin and Kaster

The Examiner rejected claims 8, 9, 11, 12-16, 21, and 23 under 35 U.S.C. § 102(b) as being anticipated by Marin, or alternatively, under 35 U.S.C. § 103(a) as being unpatentable over Marin in view of Kaster. The Examiner's rejection is respectfully traversed in view of currently amended claim 8.

Marin refers to an intraluminal stent. The stent comprises a tubular mesh-like member 10 with barbs 18 extending within openings of the member. When the stent is unexpanded, barbs 18 lie flat within the surface of member 10. When the stent is expanded, barbs 18 are caused to move radially outward from the surface of the stent. FIGS. 2 and 4 of Marin show the stent in its expanded condition.

Applicants submit that claim 8, as amended, is allowable over Marin because Marin fails to show struts that extend from a first position in which the struts are substantially parallel to an axis with which the annular structure is substantially coaxial to a second position in which the struts are radially outward and substantially perpendicular to the axis. In contrast, Marin merely shows barbs 18 that "move radially outwardly from the surface of the stent" (column 3, lines 9-10 of Marin) but fails to show the barbs in a position substantially perpendicular to an axis about which the stent is substantially coaxial. While barbs 18 of Marin are caused to move radially outwardly, the barbs remain in a position that is substantially parallel to the axis with which the stent is coaxial. Therefore, for at least this reason, applicants' submit that claim 8 is allowable over Marin.

Applicants further submit that claim 8 is patentable over the combination of Marin and Kaster because there is no suggestion or motiviation, in either the references themselves or the knowledge generally available to one of ordinary skill in the art, to combine Marin and Kaster as proposed by the Examiner.

The Examiner contends that "Kaster teaches that it was known to make similar barbs or prongs [as those shown in Marin] to extend more perpendicularly with respect to the longitudinal axis of the stent" and that therefore "it would have been obvious to have barbs, which extend more in an orthogonal direction with respect to the longitudinal axis so as to have better resistance to stent migration in both directions" (page 4, lines 5-8 of June 9, 2003 Final Office action).

Contrary to the Examiner's contention, applicants submit that Kaster does not refer to a stent device, but instead refers to a surgical staple for joining a graft vessel with a patient's body vessel through an opening in the side of the body vessel. The wall engaging members of Kaster do not resist the migration of a stent situated coaxially within a blood vessel as suggested by the Examiner. Instead, the wall engaging members are configured to engage the interior and exterior walls of a body vessel coaxially around a preformed hole in the side of the body vessel to staple a graft vessel with the body vessel. Therefore, the Examiner's contention that the wall engaging members of Kaster would better resist stent migration is speculation that is not based on any objective evidence of such a motivation.

Accordingly, at least because the Examiner has failed to provide any objective evidence, in either the references themselves or in the knowledge generally available in the art, of any motivation or suggestion for the proposed combination of Marin with Kaster, applicants submit that claim 8 is patentable over the combination of Marin and Kaster.

The Examiner further contends that as an alternative to the proposed combination of Marin with Kaster, "it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the barbs [of Marin] extend more radially outward" (page 4, lines 12-14 of Office action). Contrary to the Examiner's contention, applicants submit that the Examiner has failed to establish a prima facie case of obviousness because there is no objective evidence of any motivation or suggestion, in either Marin or the knowledge generally available to one of ordinary skill in the art, to modify barbs 18 of Marin as suggested by the Examiner. Such motivation must be found within the prior art and not in applicants' disclosure with the benefit of hindsight.

Furthermore, applicants submit that the Examiner's proposed modification of the barbs of Marin would not be an "obvious matter of design choice." The barbs of Marin are caused to extend radially outwardly by the concurrent radial deformation of the graft. Therefore, the configuration of the mesh-like structure of the graft determines how far the barbs move outward. Moreover, it is not at all clear that barbs 18 of Marin are capable of being further extended to a position that is substantially perpendicular to the graft without raising design issues that were not originally contemplated in Marin. Accordingly, applicants submit that it would not merely be an obvious design choice to have the barbs extend further radially outward.

Therefore, for at least the foregoing reasons, applicants submit that independent claim 8 and dependent claims 9, 11, 12-16, 21, and 23 are patentable over both Marin and the combination of Marin and Kaster.

B. The Rejection of Claims 8-16, 20, 21, and 23 under 35 U.S.C. 102(b) over Kaster

The Examiner rejected claims 8-16, 20, 21, and 23 under 35 U.S.C. § 102(b) as being anticipated by Kaster. This rejection is respectfully traversed in view of currently amended claim 8.

As previously noted, Kaster refers to a surgical staple for stapling two vessels together. The staple is formed on a flat sheet of material and includes interior and exterior wall engaging members which are joined by central connecting band 46. The staple is then caused to assume an annular shape by curving the connecting band about a mandrel or other appropriate object.

Applicants submit that applicants' independent claim 8 is allowable over Kaster because Kaster fails to show an annularly continuous connector structure as specified by currently amended claim 8. To the contrary, Kaster's connecting unit 46 is clearly discontinuous (see FIG. 10 of Kaster) at the convergence of the ends of connecting band 46. Therefore, for at least this reason, applicants respectfully submit that independent claim 8 and dependent claims 9-16, 20, 21, and 23 are allowable over Kaster.

C. The Rejection of Claims 17-19 and 22 under 35 U.S.C. § 103(a)

The Examiner rejected claims 17-19 under 35 U.S.C. § 103(a) as being unpatentable over Kaster in view of Dwyer. Claim 22 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Marin in view of Kaster and Kim. Applicants submit that dependent claims 17-19 and 22 are patentable at least because the foregoing remarks demonstrate that currently amended independent claim 8, from which claims 17-19 and 22 depend, is patentable.

IV. Conclusion

In view of the foregoing, applicants submit that claims 1-23 are in condition for allowance. Therefore, this application is in condition for allowance. An early and favorable action is respectfully requested.

Respectfully submitted,

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